EXHIBIT 20

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

A COMPARISON OF ALBUTEROL SULFATE PRICES

JUNE GIBBS BROWN
Inspector General

JUNE 1996
OEI-03-94-00392

EXECUTIVE SUMMARY

PURPOSE

To assess the appropriateness of the amount Medicare allows for albuterol sulfate, a prescription inhalation drug used in nebulizers.

BACKGROUND

A nebulizer is a type of durable medical equipment (DME) through which prescription drugs are administered for inhalation therapy. Patients with conditions such as asthma or emphysema may require treatment that involves the use of a nebulizer. The nebulizer is used by placing an inhalation prescription drug into its reservoir which is then converted into a fine spray by the power source and inhaled by the user.

One prescription drug that is commonly used for inhalation therapy with nebulizers is albuterol sulfate (0.083% concentration). Between January of 1994 and February of 1995, Medicare allowed $182 million for this drug, 68 percent of the $269 million in total Medicare allowances for all nebulizer drugs.

We surveyed pharmaceutical buying groups, mail-order pharmacies, and retail pharmacy stores and compared their prices for generic versions of albuterol sulfate to the amount that Medicare allows.

FINDINGS

Many pharmacies surveyed charged customers less for generic albuterol sulfate than Medicare allowed.

A customer would pay less than Medicare for albuterol sulfate in more than half of the retail stores surveyed and in all of the mail-order pharmacies contacted. Fifty-five percent of retail pharmacy stores (60 of 109) charged less for generic versions of albuterol sulfate than the $0.43 per milliliter that Medicare allowed. Four mail-order pharmacies charged between 2 and 12 percent less than Medicare reimburses, and one charged 53 percent less.

All five buying groups surveyed had negotiated prices substantially lower than Medicare reimbursement for albuterol sulfate.

The generic drug prices the five buying groups negotiated ranged from 56 to 70 percent less than the $0.43 Medicare allowed per milliliter of albuterol sulfate. The pharmacies that are members of these buying groups purchase albuterol sulfate at these lower prices. Therefore, the average wholesale price used to determine

Medicare's allowance for albuterol sulfate was significantly higher than the wholesale price paid by thousands of the buying groups' member pharmacies.

RECOMMENDATION

We believe the findings of this report complement and reinforce those of our earlier report, *Medicare Payments for Nebulizer Drugs*, by providing evidence that Medicare's allowance for nebulizer drugs may be inappropriately high. In the earlier report, we found that Medicaid State agencies were reimbursing less for albuterol sulfate than Medicare. We have provided evidence in this report that mail-order pharmacies and many retail pharmacy stores charge customers less for generic versions of albuterol sulfate than Medicare allows. Currently, the DMERCs are utilizing the median of average wholesale prices for generic versions of albuterol sulfate to determine the allowance amount. We believe using the median of the published average wholesale prices does not reflect the actual wholesale pricing of albuterol sulfate that is occurring in the marketplace.

We therefore continue to believe that **HCFA should reexamine its Medicare drug reimbursement methodologies with the goal of reducing payments for prescription drugs**, as we recommended in our earlier report.

AGENCY COMMENTS

The HCFA concurred with our recommendation. In exploring new strategies for changing Medicare's payment for prescription drugs, HCFA has constructed a framework to calculate drug prices centrally. They are also reviewing other approaches that could improve Medicare drug reimbursement. For the complete text of HCFA's comments, see Appendix A.

OIG RESPONSE

We support HCFA's efforts to revise its drug reimbursement mechanisms to more appropriately pay for prescription drugs covered under the Medicare program. We believe revisions to the current payment methodologies that take into account the actual costs of these drugs would provide significant savings to the Medicare program.

TABLE OF CONTENTS

INTRODUCTION

PURPOSE

To assess the appropriateness of the amount Medicare allows for albuterol sulfate, a prescription inhalation drug used in nebulizers.

BACKGROUND

A nebulizer is a type of durable medical equipment (DME) through which prescription drugs are administered for inhalation therapy. It consists essentially of two components: (1) a power source such as an air compressor or ultrasonic device, and (2) a dispensing mechanism consisting of flexible tubing, a mouthpiece, and liquid reservoir. Patients with conditions such as asthma or emphysema may require treatment that involves the use of a nebulizer. The nebulizer is used by placing an inhalation prescription drug into its reservoir which is then converted into a fine spray by the power source and inhaled by the user.

One prescription drug that is commonly used for inhalation therapy with nebulizers is albuterol sulfate (0.083% concentration). Between January of 1994 and February of 1995, Medicare allowed $182 million for albuterol sulfate (code J7620). This represents 68 percent of the $269 million in total Medicare allowances for all nebulizer drugs. Medicare allowances for all nebulizer drugs have increased more than 200 percent between 1992 and 1994.

Payment of Nebulizer Drugs in the Medicare Program

Title XVIII of the Social Security Act authorizes coverage of DME under Medicare Part B. Section 2100.5 of the Medicare Carriers Manual specifies instances involving covered uses of outpatient prescription drugs, including drugs used in conjunction with DME. The Manual specifies that drugs are covered under Medicare Part B as long as the drugs are necessary for the effective use of the DME. This includes inhalation drugs used in nebulizers.

According to 42 Code of Federal Regulations 405.517, Medicare computes an allowed amount for drugs based on the lower of the Estimated Acquisition Cost (EAC) or the national Average Wholesale Price (AWP). The allowed amount is the price that Medicare and its beneficiaries pay a drug supplier. If a drug has multiple sources (as does albuterol sulfate), the price is based on the lower of the EAC or the median of the national AWP for all generic sources. The EAC is determined based on surveys of the actual invoice prices paid for the drug. The AWP is determined through *The Red Book* or similar price listings used in the pharmaceutical industry.

The Health Care Financing Administration (HCFA) designated four Durable Medical Equipment Regional Carriers (DMERCs) to process all claims for durable medical

equipment, prosthetics, orthotics, and supplies, including nebulizer drugs. Effective October 1, 1993, the DMERCs replaced the local carriers which had previously processed these claims. Each DMERC is responsible for determining the pricing for albuterol sulfate in their regions based on the computation stated in the regulations.

Related Work by the Office of Inspector General

In a recent report entitled, *Medicare Payments for Nebulizer Drugs* (OEI-03-94-00390), the OIG found that Medicaid reimbursed albuterol sulfate and other nebulizer drugs at significantly lower prices than Medicare. For albuterol sulfate, Medicare and its beneficiaries paid $34 million more in 17 States than the amount that Medicaid would have paid. In a related report, *Suppliers' Acquisition Costs for Albuterol Sulfate* (OEI-03-94-00393), Medicare's allowances for albuterol sulfate were found to substantially exceed suppliers' actual acquisition costs for the drug.

This inspection was conducted as part of Operation Restore Trust (ORT). The initiative, focused in five States, involves multi-disciplinary teams of State and Federal personnel seeking to reduce fraud, waste, and abuse in nursing homes, hospices, home health agencies, and by durable medical equipment suppliers.

METHODOLOGY

For the purposes of comparing pricing information, we collected data from pharmaceutical purchasing organizations or buying groups, mail-order pharmacies, and retail pharmacy stores. We used Medicare's allowed amount for this comparison. The allowed amount includes the 80 percent the Medicare program pays directly to the supplier and the 20 percent copayment for which the beneficiary is responsible.

Since albuterol sulfate (0.083% concentration) is a multiple source drug with both brand and generic versions, the DMERCs base their reimbursement on the lower of the estimated acquisition cost (EAC) or the median of the national average wholesale price (AWP) for all generic sources. At the present time, the four DMERCs base their reimbursement allowance on the AWP for the generic sources of albuterol sulfate. Due to the fact that Medicare uses the prices of generic drugs to compute reimbursement for albuterol sulfate, we compared Medicare's reimbursement amount with the prices that buying groups negotiated or pharmacies charged for the generic versions of albuterol sulfate.

The pricing for albuterol sulfate, during the time of our beginning survey work in April 1995, was $0.43 per milliliter in three DMERCs and $0.40 in one DMERC. Since 90 percent of the albuterol sulfate paid for by the DMERCs in 1994 was in the three DMERCs with reimbursement of $0.43, we believe it is fair to use this single price for comparison purposes. The allowance for albuterol sulfate can be updated on a quarterly basis by the DMERCs. Since the time of our inspection work, one DMERC has increased the allowance amount, one has decreased the allowance amount, and

two remain at $0.43. We have chosen to use $0.43 as the Medicare allowance since that was the amount that was in effect at the start of our data collection.

Survey of Buying Groups and Mail-Order Pharmacies

Using a standardized data collection instrument, we obtained pricing information on albuterol sulfate from buying groups and mail order pharmacies. We surveyed five buying groups which were considered prominent within the industry. The groups ranged in size from 970 to 2500 member stores nationwide. Buying groups negotiate prices for prescription drugs from drug manufacturers/suppliers. Pharmacies that belong to the buying groups are able to purchase drugs based on these negotiated prices. We also selected five of the largest mail-order pharmacies that did not require customers to be a member of a particular insurance plan but would service any eligible person. However, for one of the mail-order pharmacies, the customer had to be a member of a senior citizen organization and the membership fee for joining the organization was factored into the price. We also obtained any additional fees such as shipping and handling or membership fees that might be charged by the mail-order pharmacies. We factored these charges into the prices.

Survey of Retail Pharmacy Stores

Using a standardized data collection instrument, we contacted retail pharmacy stores in four States to determine their prices for albuterol sulfate. We purposefully selected four States (California, Florida, Missouri, and North Carolina) for which statewide information on pharmacies was available through our Office of Audit Services (OAS). For each State, we randomly selected 35 retail chain pharmacies. Ninety-six percent of the pharmacies in our survey (134 of 140) provided information to us. Seventy-eight percent of the retail pharmacies (109 of 140) provided us with prices for the generic versions of albuterol sulfate.

This inspection was conducted in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

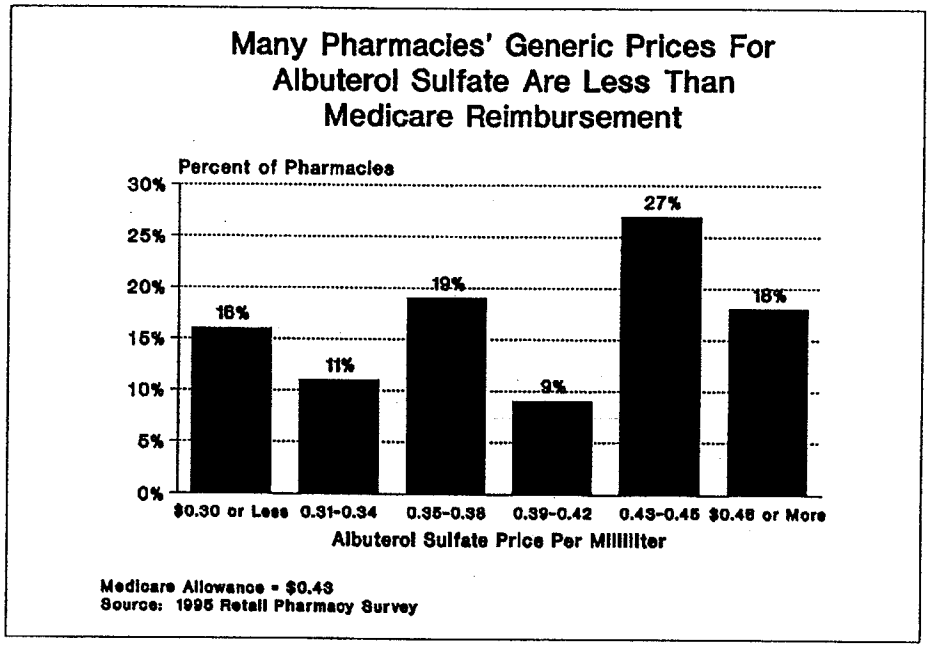
FINDINGS

MANY PHARMACIES SURVEYED CHARGED CUSTOMERS LESS FOR GENERIC ALBUTEROL SULFATE THAN MEDICARE ALLOWED.

A customer would pay less than Medicare for albuterol sulfate in more than half of the retail stores surveyed and in all of the mail-order pharmacies contacted.

More than half of retail pharmacies surveyed charged customers less for generic albuterol sulfate than Medicare allowed.

Fifty-five percent of retail pharmacy stores (60 of 109) charged less for generic versions of albuterol sulfate than the $0.43 per milliliter that Medicare allowed. The chart below summarizes the prices that pharmacies charged for albuterol sulfate.



Many of the pharmacies' prices were significantly less than the amounts Medicare and its beneficiaries paid for albuterol sulfate. Sixteen percent of pharmacies charged at least 30 percent less for generic versions of albuterol sulfate than Medicare would have allowed for the same drugs. Eleven percent of pharmacies had prices between 20 and 30 percent less than Medicare. Almost one-fifth of pharmacies (19 percent) charged between 10 and 19 percent less than the Medicare allowance of $0.43. In addition, more than one-third of pharmacies in our survey (39 percent) provide a further discount to senior citizens purchasing prescription drugs.

All five mail-order pharmacies charged less than the Medicare allowance for albuterol sulfate.

All five of the mail-order pharmacies charged their customers less for albuterol sulfate then Medicare and its beneficiaries paid for albuterol sulfate. Four of these pharmacies' charges ranged from $0.38 to $0.42, or between 2 to 12 percent less than Medicare allowances per milliliter of drug. One of them charged only $0.20, or 53 percent less. If a Medicare beneficiary received 375 milliliters of albuterol sulfate per month for inhalation therapy, Medicare and the beneficiary would save anywhere from $4 to $87 a month if Medicare based its reimbursement on the prices charged by these mail order companies. The savings to Medicare and its beneficiaries could be even greater since four of the mail-order companies offer lower prices when larger volumes of drugs are purchased. For the example used above of 375 milliliters of albuterol sulfate, these pharmacies would have charged an additional 2 to 20 percent less per milliliter.

ALL FIVE BUYING GROUPS SURVEYED HAD NEGOTIATED PRICES SUBSTANTIALLY LOWER THAN MEDICARE REIMBURSEMENT FOR ALBUTEROL SULFATE.

The generic drug prices that five buying groups negotiated ranged from 56 to 70 percent less than the $0.43 Medicare allowed per milliliter of albuterol sulfate. The thousands of pharmacies that are members of these buying groups purchase albuterol sulfate for the prices listed in the table below. These prices were significantly lower than the average wholesale prices for generic drugs that the DMERCs had been using to establish the pricing for albuterol sulfate.

Price for Generic Version of Albuterol Sulfate

Type of Payer	Price per milliliter
Medicare Allowance	$0.43
Pharmaceutical Buying Groups	$0.13/$0.15[1]
	$0.16
	$0.16
	$0.18
	$0.18/$0.19[1]

[1] Provided prices for more than one manufacturer of generic albuterol sulfate.

The buying groups were able to offer lower drug purchase prices to their member pharmacies because they negotiate prices directly with drug manufacturers/suppliers. The member pharmacy would then purchase the prescription drug at the negotiated price plus a wholesaler upcharge. The upcharge is a percentage of the negotiated price that is applied to their members' purchases. The upcharges that members of

these five buying groups paid ranged from 3 to 6 percent. The prices in the table include these upcharges and thereby represent a pharmacy's total wholesale purchase price for one milliliter of albuterol sulfate. Therefore, the average wholesale price used to determine Medicare's allowance for albuterol sulfate was more than double the wholesale price paid by thousands of the buying groups' member pharmacies.

RECOMMENDATION

We believe the findings of this report complement and reinforce those of our earlier report, *Medicare Payments for Nebulizer Drugs*, by providing evidence that Medicare's allowance for nebulizer drugs may be inappropriately high. In the earlier report, we found that Medicaid State agencies were reimbursing less for albuterol sulfate than Medicare. We have provided evidence in this report that mail-order pharmacies and many retail pharmacy stores charge customers less for generic versions of albuterol sulfate than Medicare allows. Currently, the DMERCs are utilizing the median of average wholesale prices for generic versions of albuterol sulfate to determine the allowance amount. We believe using the median of the published average wholesale prices does not reflect the actual wholesale pricing of albuterol sulfate that is occurring in the marketplace.

We therefore continue to believe that HCFA should reexamine its Medicare drug reimbursement methodologies with the goal of reducing payments for prescription drugs, as we recommended in our earlier report.

For our readers' convenience, we repeat here the options contained in our prior report for changing Medicare's payment for prescription drugs.

Discounted Wholesale Price

Many State agencies use a discounted AWP to establish drug prices. Medicare should have a similar option. Medicare could base its drug payment on the lower of a discounted AWP or the median of the AWP for all generic sources, whichever results in the lower cost to Medicare and its beneficiaries. To implement this recommendation, HCFA would have to revise Medicare's claims coding system which does not identify the manufacturer or indicate if the drug is a brand name or a generic equivalent, information that is needed to discount the AWP and obtain a rebate for a specific drug. Medicaid uses the National Drug Code (NDC) in processing drug claims. The NDC identifies the manufacturer and reflects whether the drug is a brand name or a generic equivalent.

Manufacturers' Rebates

Medicare could develop a legislative proposal to establish a mandated manufacturers' rebate program similar to Medicaid's rebate program. We recognize that HCFA does not have the authority to simply establish a mandated manufacturers' rebate program similar to the program used in Medicaid. Legislation was required to establish the Medicaid rebate program, and would also be required to establish a Medicare rebate program. We have not thoroughly assessed how a Medicare rebate program might operate, what administrative complexities it might pose, or how a Medicare rebate program might differ from a Medicaid rebate program. We believe, however, the legislative effort would be worthwhile. The same manufacturers that provide rebates

to Medicaid make the drugs that are used by Medicare beneficiaries and paid for by the Medicare program.

Competitive Bidding

Medicare could develop a legislative proposal to allow it to take advantage of its market position. While competitive bidding is not appropriate for every aspect of the Medicare program or in every geographic location, we believe that it can be effective in many instances, including the procurement of drugs. Medicare could ask pharmacies to compete for business to provide Medicare beneficiaries with prescription drugs. All types of pharmacies could compete for Medicare business, including independents, chains, and mail-order pharmacies.

Inherent Reasonableness

Since Medicare's guidelines for calculating reasonable charges for drugs result in excessive allowances, the Secretary can use her "inherent reasonableness" authority to set special reasonable charge limits. If this option is selected, however, it will not be effective unless the Secretary's authority to reduce inherently unreasonable payment levels is streamlined. The current inherent reasonableness process is resource intensive and time consuming, often taking two to four years to implement. Medicare faces substantial losses in potential savings--certainly in the millions of dollars--if reduced drug prices cannot be placed into effect quickly.

Acquisition Cost

Medicare could base the payment of drugs on the EAC. The DMERCs currently have this option; however, HCFA has been unsuccessful in gathering the necessary data to fully implement it. Once the problem of gathering the necessary data is overcome, the use of the EAC would result in lower allowed amounts. A variation of this option is to use actual rather than estimated acquisition cost.

AGENCY COMMENTS

The HCFA concurred with our recommendation to reexamine Medicare's drug reimbursement methodologies with a goal of reducing payments. In exploring new strategies for changing Medicare's payment for prescription drugs, HCFA has constructed a framework to calculate drug prices centrally. They have also developed a crosswalk between Medicare's current coding system and the National Drug Codes (NDCs) to enable claims processing using the NDC. In addition, HCFA is examining the use of competitive bidding for nebulizers and associated drugs under its demonstration authority.

The HCFA agreed with our concerns about invoking the inherent reasonableness authority and stated that it appreciated the OIG's work in this area. The HCFA is

currently addressing this issue through the regulatory process. The full text of HCFA's comments are presented in Appendix A.

OIG RESPONSE

We support HCFA's efforts to revise its drug reimbursement mechanisms to more appropriately pay for prescription drugs covered under the Medicare program. We believe revisions to the current payment methodologies that take into account the actual costs of these drugs would provide significant savings to the Medicare program.

EXHIBIT 21

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

EXCESSIVE MEDICARE REIMBURSEMENT FOR ALBUTEROL

JANET REHNQUIST
Inspector General

MARCH 2002
OEI-03-01-00410

TABLE OF CONTENTS

the number of milliliters of albuterol solution by 0.833 to determine the milligram amount, e.g., 75 ml of solution multiplied by 0.833 equals 62.5 mg. We then divided the drug price by the number of milligrams to determine a per mg price.

Department of Veterans Affairs Prices

To determine the VA's current costs for albuterol, we obtained a file from the VA website containing their 2001 contracted prices. The VA pricing file contained Federal Supply Schedule prices for 11 of the 19 matching albuterol national drug codes. To determine a single VA price, we calculated the median price per mg for these 11 codes.

We also compared the 2001 VA prices to VA prices in the years 1998 through 2000. We determined the percentage change each year in VA prices, and multiplied this number by the amount Medicare paid in a given year. These figures represent the amount Medicare total payments would have increased or decreased if the Medicare reimbursement amount changed at the same rate as the VA price. In order to estimate this figure for 2001, we assumed that 2001 Medicare payments for albuterol would equal 2000 payments.

Prices Available to Suppliers and Wholesalers

To determine actual wholesale prices for albuterol, we reviewed year 2001 print and online catalogs from four drug wholesalers and two group purchasing organizations. The six pricing sources we used provide drug products to suppliers and physician practices. We then computed a single catalog price for albuterol by calculating the median price per mg of the corresponding national drug codes.

In addition to catalog prices, we also used actual albuterol invoices to determine supplier acquisition costs. The invoices were collected by the OIG during a review of inhalation drug utilization. The invoices were obtained during site visits to suppliers throughout the country, and were for albuterol purchased between June 1998 and August 2000. To determine a single invoice price, we calculated the median price per mg for the 91 invoice prices collected from suppliers.

We also obtained manufacturer-reported wholesale acquisition costs from the April 2001 CD-ROM edition of *Drug Topics Red Book*. The *Drug Topics Red Book* defines wholesale acquisition cost as manufacturer-quoted list prices to wholesale distributors; these prices are not reflective of bids, rebates, volume purchase agreements, or other types of exclusive contracts. Eleven of the 19 albuterol national drug codes had wholesale acquisition costs

reported in 2001. From these costs, we calculated a median per mg wholesale acquisition cost for albuterol.

Calculating Potential Medicare Savings

To calculate potential Medicare savings, we compared Medicare's reimbursement amount for 1 mg of albuterol to VA prices, wholesale acquisition costs, catalog prices, and invoice prices. We determined the percentage difference in prices by subtracting the median source price from the Medicare price, and then dividing this number by the Medicare price. These percentages indicate how much Medicare would save if reimbursement for albuterol were based on prices provided by other sources. We then multiplied these percentages by the total amount Medicare paid for albuterol in 2000 to calculate dollar savings. A table showing the data used to calculate potential savings is presented in Appendix B.

This inspection was conducted in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

FINDINGS

Medicare and its beneficiaries would save $264 million a year if albuterol were reimbursed at the price paid by the VA

The Medicare reimbursement amount for albuterol is over nine times greater than the median VA price

The median Federal Supply Schedule price available to the VA for generic albuterol is only $0.05 per mg, compared to $0.47 per mg for Medicare. We estimate that Medicare and its beneficiaries would save $264 million a year if reimbursement for albuterol were set at the median amount paid by the VA under the Federal Supply Schedule. The savings represent 89 percent of the $296 million Medicare paid for albuterol in 2000.

Medicare beneficiaries would receive $53 million of the $264 million in savings through reduced coinsurance payments. A Medicare beneficiary using a typical monthly amount of albuterol (250 mg) would pay $23.50 in Medicare coinsurance. That coinsurance amount is nearly double what the VA would pay outright ($12.50) to purchase one month's supply of the drug. Table 1 below compares the Medicare reimbursement amount to median prices available through other sources. It also provides Medicare savings and beneficiary coinsurance based on various reimbursement levels.

TABLE 1: COMPARISON OF ALBUTEROL PRICES

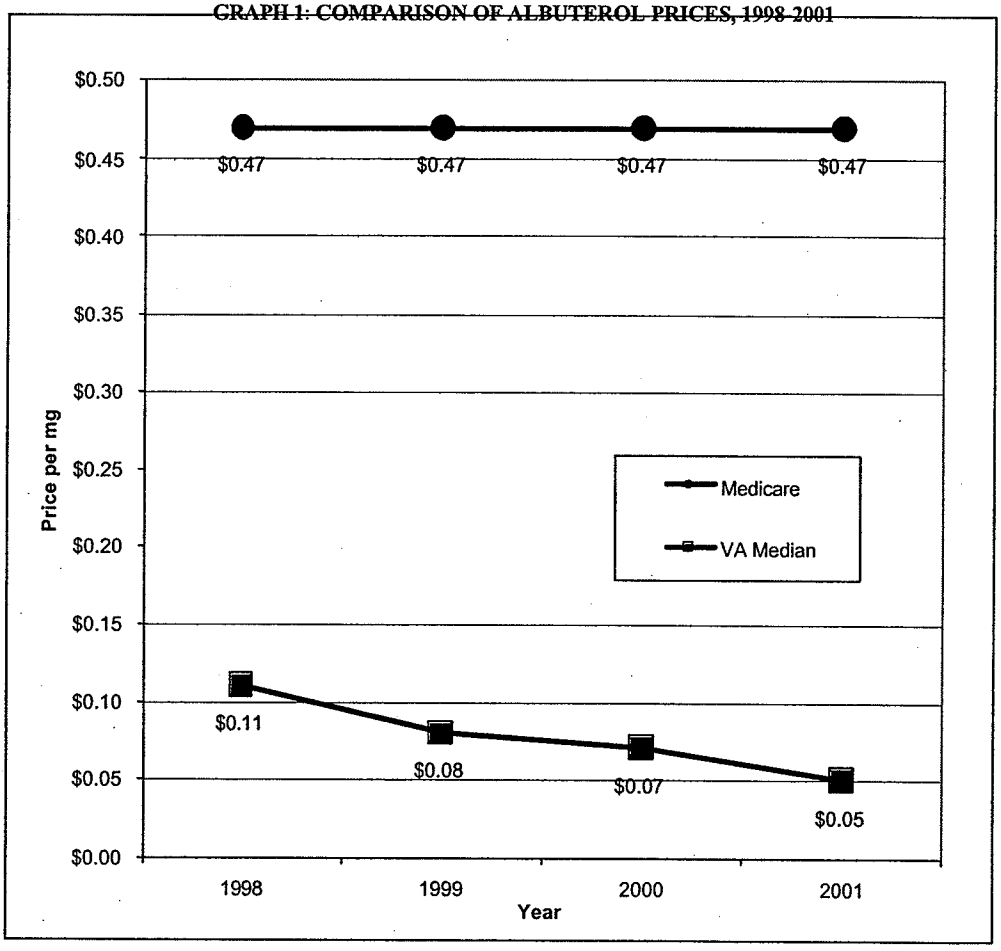
Pricing Source	Median Price per mg	Cost of Typical Individual Monthly Usage (250 mg)	Monthly Medicare Beneficiary Coinsurance Based on Source Price	Potential Annual Medicare and Beneficiary Savings
Medicare	$0.47	$117.50	$23.50	N/A
Department of Veterans Affairs	$0.05	$12.50	$2.50	$264,222,803
Wholesale Catalogs	$0.08	$20.00	$4.00	$245,349,746
Supplier Invoices	$0.09	$22.50	$4.50	$239,058,727
Wholesale Acquisition Cost	$0.11	$27.50	$5.50	$226,476,689

Sources: 2001 Medicare Carrier and Department of Veterans Affairs Websites, 2001 Wholesale Catalogs, 1998-2000 Supplier Invoices Collected by OIG, 2001 *Drug Topics Red Book*

Between 1998 and 2001, the median VA cost for albuterol decreased by over 50 percent, while the Medicare reimbursement amount remained the same

The VA price for albuterol has fallen by more than 50 percent over the last three years, from $0.11 per mg in 1998 to $0.05 per mg in 2001. During the same time period, Medicare's reimbursement amount (based on reported average wholesale prices) has remained constant at $0.47 per mg. If the Medicare reimbursement amount for albuterol decreased at a rate equal to the VA's purchase price, Medicare and its beneficiaries would have saved $68 million in 1999 and $108 million in 2000. The program could save another $161 million in 2001. The graph below illustrates the changes in VA and Medicare pricing over the last 3 years.

GRAPH 1: COMPARISON OF ALBUTEROL PRICES, 1998-2001



Sources: Medicare Carrier and Department of Veterans Affairs Websites

Medicare and its beneficiaries would save between $226 million and $245 million a year if albuterol were reimbursed at prices available to wholesalers and suppliers

Medicare payments for albuterol would be reduced by 83 percent if reimbursement amounts were based on prices listed in wholesale catalogs

Medicare and its beneficiaries would save $245 million a year if the reimbursement amount for albuterol equaled the median price available to suppliers through wholesalers and group purchasing organizations. This represents 83 percent of the $296 million Medicare and its beneficiaries reimbursed for the drug in 2000. Catalog prices for generic albuterol ranged from a low of $0.07 per mg to a high of $0.15 per mg. The Medicare reimbursement amount ($0.47 per mg) was nearly six times more than the median catalog price ($.08 per mg).

Like VA prices, catalog prices for albuterol have gone down over the last several years. In earlier reports, we found that the average catalog price for albuterol was $0.23 per mg in 1996, and $0.13 per mg in 2000. The current catalog price of $0.08 per mg of albuterol is 65 percent less than the catalog price of the drug five years earlier.

Medicare payments for albuterol would be reduced by 81 percent if reimbursement amounts were based on supplier invoice prices

Invoices reviewed by the OIG listed prices ranging from $0.08 to $0.14 per mg for albuterol purchased by suppliers between 1998 and 2000. The median price for albuterol purchased by these suppliers was $0.09 per mg, 81 percent less than the Medicare reimbursement amount. Medicare and its beneficiaries would save $239 million a year if albuterol were reimbursed at the median invoice price.

Medicare payments for albuterol would be reduced by 77 percent if reimbursement amounts were based on manufacturer-reported wholesale acquisition costs

Published wholesale acquisition costs for albuterol ranged from $0.09 to $0.18 per mg in April 2001. The median wholesale acquisition cost was $0.11 per mg. Individual drug manufacturers reported these wholesale acquisition costs to *Drug Topics Red Book*. The *Drug Topics Red Book* defines wholesale acquisition cost as manufacturer-quoted list prices

to wholesale distributors, not reflective of bids, rebates, volume purchase agreements, or other types of exclusive contracts.

If Medicare based its reimbursement for albuterol on manufacturer-reported wholesale acquisition costs rather than average wholesale prices, the program and its beneficiaries would save $226 million a year.

Less than one percent of albuterol suppliers were responsible for providing the majority of the product to Medicare beneficiaries in 2000

Medicare reimbursed 6,522 suppliers for albuterol claims in 2000. However, just 34 of these suppliers received more than $1 million each in Medicare reimbursement for albuterol in 2000, with five having between $11 million and $35 million in paid claims. These 34 suppliers, who all provided home-delivery/mail-order services to beneficiaries, received 63 percent of the Medicare payments for albuterol in 2000. Therefore, the majority of the albuterol supplied to Medicare beneficiaries was provided by suppliers that purchase a large quantity of the product. We believe that suppliers that purchase albuterol in such large quantities may receive volume discounts from manufacturers and wholesalers.

RECOMMENDATION

Medicare should reduce excessive reimbursement amounts for albuterol

Despite numerous attempts by the Centers for Medicare & Medicaid Services (CMS) to lower reimbursement amounts for prescription drugs, the findings of this report illustrate that Medicare still pays too much for albuterol. We have consistently found that the published average wholesale prices currently used by Medicare to establish reimbursement amounts bear little or no resemblance to actual wholesale prices that are available to suppliers and large government purchasers.

We understand that unlike most drugs covered by Medicare, albuterol is usually provided by suppliers rather than administered by physicians. These suppliers obviously need to make a profit from the products they provide, yet the spread between what Medicare reimburses for albuterol and the price at which suppliers are able to purchase the drug is significant. Reimbursement levels for albuterol not only impact the Medicare program, but also affect Medicare beneficiaries who pay increased coinsurance amounts.

We offer the following options for reducing excessive reimbursement amounts for covered drugs:

- Authorizing a commission to set payment rates.
- Calculating national estimated acquisition costs based upon the average manufacturer prices reported to the Medicaid program.
- Collecting more accurate average wholesale prices from drug pricing catalogs or other sources.
- Increasing the discount off the published average wholesale prices.
- Basing payment on physician/supplier acquisition costs.
- Establishing manufacturers' rebates similar to those used in the Medicaid program.
- Creating a fee schedule for covered drugs based on the Federal Supply Schedule.

- Using CMS' inherent reasonableness authority.
- Using competitive bidding.

Agency Comments

The CMS agreed that the amounts being reimbursed for drugs in the Medicare program are excessive, and that it is clear that the payment system for outpatient drugs needs revision. The agency noted that it must find a way to ensure that the program pays appropriately for all Medicare benefits, including covered drugs and the services required to furnish those drugs. The CMS went on to state that they are looking forward to working with the Congress and the OIG to revise the Medicare payment system for prescription drugs. The full text of CMS' comments is presented in Appendix C.

EXHIBIT 22

FILED UNDER SEAL

EXHIBIT 23

FILED UNDER SEAL